NORTH AMERICAN SPINE SOCIETY

A NON-PROFIT CORPORATION

7/19/2000

Kathy Eberhart
Food & Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Suite 200 North
Rockville, MD 20852-1448
HFM 42

Dear Ms. Eberhart:

As the President of the North American Spine Society (NASS), I represent over 2,500 members of NASS who span the entire spectrum of the surgical and non-surgical care of the spine patient. However, as you will soon realize, the implications of regulating allograft bone as a device go far beyond the care of the patient with spine disease.

For years allograft bone processed and obtained primarily through regional or local tissue banks has been used to treat a wide array of musculoskeletal disease. Not restricted to use only in the spine, allograft is routinely used to replace or augment a patient's own bone following severe trauma, infection, joint replacement, reconstruction of traumatic injuries and congenital abnormalities and following bone tumor resection. In these instances when a patient's own bone is not available or is insufficient to allow proper treatment, allograft bone has for years been a safe, clinically proven and reliable alternative where there are no other viable options.

In addition to these clinically diverse applications of allograft bone, it has also served the spine surgeon well over the years when autograft was not available or insufficient. Whether used as a bone dowel in anterior cervical fusions, anterior vertebral body replacement following trauma or tumor excision, lumbar vertebral body replacement in patients with degenerative disc disease or simply as an augment to posterolateral spine fusion, allograft has been a dependable and safe alternative to autograft.

With the advent of more sophisticated postmortem screening of allograft bone, the risk of contagious disease has been significantly reduced to statistically acceptable levels, so that the safety of allograft bone has never been more predictable. Then why, with such diverse and time proven uses of allograft bone, do allograft bone dowels need further regulatory scrutiny?

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With the current stringent regulatory control of allograft bone, perhaps the first question we must ask, is why the FDA needs further regulatory control. Exactly what data does the FDA need that currently is not available?

What impact will the added regulatory control have on the ability of the tissue banks to continue to provide allograft bone for use in the many clinical settings in which there may be no reasonable alternative? Most of the regional or local tissue banks that process allograft bone are non-profit and not equipped or financially able to conduct regulated pre-clinical studies and clinical trials that would be required if bone dowels become regulated as a device. It would be just a matter of time before these non-profit tissue banks would simply be financially unable to process and provide allograft bone. As these non-profits leave the marketplace, two unacceptable consequences would occur. Allograft bone would no longer be available or its processing would come under the control of for profit companies which would ultimately result in escalating the cost of the allograft.

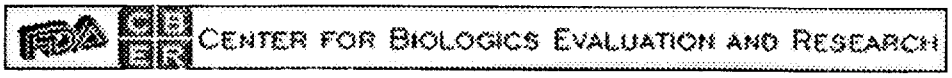
Another question we must ask ourselves has more to do with regulatory practicality. If bone dowels to be used for lumbar vertebral interbody fusions are to be regulated as devices when will we see the need to regulate allograft used to augment a load bearing total hip replacement or a load bearing allograft used in tibial or femoral tumor replacement? Allografts have been used for decades as load bearing autograft substitutes in anterior cervical fusions. Must we now subject them to regulated pre-clinical studies and clinical trials to verify their safety and effectiveness as devices? At what point does regulatory control stop? Who is to decide which allograft configuration is to be considered "a device" and others just "a plain old" reliable and safe alternative to autograft?

Without a doubt the contentious regulatory issues surrounding the pedicle screw have caused all of us, the surgeons as well as the FDA, to approach emerging techniques involving the spine with conservatism, but let us put science and the practice of clinical medicine in its' proper perspective. If we now begin to treat allograft bone as a device, clinically safe and proven applications of this alternative to a patients' own bone may no longer be available and newer uses such as the bone dowel for anterior lumbar fusions may never become available. This would be regrettable not only for the continuing evolution of clinical medicine, but more importantly patients who may have no other source of bone other than allograft may suffer the most. To begin regulating the interbody allograft bone dowel as a medical device may be the first step in opening a Pandora's box of allograft bone regulatory nightmares not only for the FDA, but also for surgeons and patients as well.

Sincerely,

Neil Kahanovitz, MD
President

NK: ck



Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair

National Institutes of Health (NIH)
NIH Clinical Center, Building 10
Jack Masur Auditorium
9000 Rockville Pike
Bethesda, MD
August 2 , 2000
8:30 - 5:00

The Food and Drug Administration is announcing a public meeting entitled "Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair." The goals of this meeting are to provide a public forum for gathering scientific data, information and views from interested persons about human bone allograft in relation to FDA's proposed tissue rules.

This public meeting is being organized by the Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH) to provide stakeholders with the opportunity to present additional information to the agency. The agency is requesting specific information concerning the characteristics of various bone products as they relate to the agency's proposed definitions for minimal manipulation and homologous use. Stakeholders are encouraged to provide information concerning:

- Which processing procedures applied to human bone allograft fall within, or outside of, FDA's proposed definition for minimal manipulation?
- Which uses of human bone allograft fall within, or outside of, FDA's proposed definition for homologous use?
- What risks to health have been identified and characterized for human bone allograft products?
- What controls have been identified to adequately address the risks to health of use of human bone allograft products?
- What industry standards for bone allograft products are available, and what standards will be needed in the future?

Registration Information:

Fax registration information (including name, title, firm name, address, telephone number, and fax number) to Kathy Eberhart by July 24th. If you wish to make an oral presentation

please fill out the attached form and fax to Kathy.

For further information contact:

Kathy Eberhart, FDA,
Center for Biologics Evaluation and Research
301-827-1317 (phone)
301-827-3079 (fax)
Email: eberhart@cber.fda.gov

More details will be provided in a soon to be published Federal Register notice.

Presentation Form

*Last Updated: **6/30/2000***

Notice of Intent to Participate
in the
Food and Drug Administration Open Public Meeting
concerning

Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair

Name: _____

Title: _____

Affiliation: _____

Representing: _____
(if different from affiliation)
Address: _____

_____

Phone Number: _____

Fax Number: _____

Title of Presentation: _____

AV equipment needed: _____

Approximate time needed: _____

Please fax this form to Kathy Eberhart at 301-827-3079 by July 24th with a brief summary of your presentation for the docket.

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22 CALENDAR COURT, 2ND FLOOR, LAGRANGE, ILLINOIS 60625 USA

Kathy Eberhart

Food & Drug Administration

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